

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2006/001059

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.

A61K 31/728 (2006.01) *A61P 1/00* (2006.01) *A61P 35/00* (2006.01)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
MEDLINE, CAPLUS, WIPDS; Hyaluronan, hyaluronic acid, hyaluronate, beta-glucuronidase, treatment, therapy,
A61K 31/728 (2006.01)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2003/018062 A1 (MEDITECH RESEARCH LIMITED) 06 March 2003 See Examples 5, 6 and 7; page 16 lines 1-2; page 13 lines 4-12 and page 16 lines 12-17.	1-3, 11-14, 17, 20-28 35-38, 41, and 44-48
X	WO 2002/005852 A1 (MEDITECH RESEARCH LIMITED) 24 January 2002 See Example 3; description of figures; page 9 lines 30-34 and page 10 lines 30-37.	1-3, 11-14, 17, 20-28 35-38, 41, and 44-48
X	WO 2000/041730 A1 (MEDITECH RESEARCH LIMITED) 20 July 2000 see Summary of the Invention; Examples 2 and 10; page 17 line 37 and page 9 lines 30-34	1-3, 17, 20-28 41, and 44-48

☒ Further documents are listed in the continuation of Box C☒ See patent family annex

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier application or patent but published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search
22 August 2006

Date of mailing of the international search report

22 SEP 2006

Name and mailing address of the ISA/AU

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	ROSENTHAL et al. "Phase I and pharmacokinetic evaluation of intravenous hyaluronic acid in combination with Doxorubicin or 5-Fluorouracil." Chemotherapy, 09 May 2005 Vol. 51, pages 132-141. See page 136 column 1 last paragraph; 140 column 2 last paragraph; and page 135 third paragraph.	1-3, 17, 20-28 41, and 44-48
X	WO 1997/020564 A1 (HYAL PHARMACEUTICAL CORPORATION) 12 June 1007 See Summary of the Invention; page 8 lines 15-26 and 28-36; page 10 line 4 – page 13 line 2.	1-4, 11, 14, 17, 20-29, 35, 38, 41, and 44-48
X	WO 1995/030423 A1 (NORPHARMCO INC.) 16 November 1995 See Summary of the Invention and page 14 line 5 – page 18 line 2.	1-4, 17, 20-29, 41, and 44-48
X	WO 1991/004058 A2 (NORPHARMCO INC.) 04 April 1991 See Summary of the Invention	1-4, 11, 14, 17, 20-29, 35, 38, 41, and 44-48

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
See supplementary box

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-48

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

Supplemental Box

(To be used when the space in any of Boxes I to VIII is not sufficient)

Continuation of Box No: III

This International Application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept.

In assessing whether there is more than one invention claimed, I have given consideration to those features which can be considered to potentially distinguish the claimed combination of features from the prior art. Where different claims have different distinguishing features they define different inventions.

This International Searching Authority has found that there are different inventions as follows:

- 1) Claims 1-48 directed to formulations comprising hyaluronan (HA) and a therapeutic agent, or methods of treatment comprising administration of said formulation wherein said treatment modulates the activity of beta-glucuronidase.
- 2) Claims 49-53 directed to a pharmaceutical composition comprising a formulation comprising hyaluronan (HA) and a therapeutic agent, when used to treat cancer.
- 3) Claims 54-56 directed to a method of treatment comprising administration of a formulation comprising hyaluronan (HA) and a therapeutic agent, wherein said formulation or a component thereof modulates the activity of drug transport proteins.

PCT Rule 13.2, first sentence, states that unity of invention is only fulfilled when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. PCT Rule 13.2, second sentence, defines a special technical feature as a feature which makes a contribution over the prior art.

The only feature common to all of the claims is the formulation comprising hyaluronan (HA) and a therapeutic agent. However this concept is not novel in the light of:

WO 2002005852 A1 (MEDITECH RESEARCH LIMITED) 24 January 2002, which discloses compositions comprising hyaluronan and a chemotherapeutic agent.

This means that the common feature can not constitute a special technical feature within the meaning of PCT Rule 13.2, second sentence, since it makes no contribution over the prior art.

Because the common feature does not satisfy the requirement for being a special technical feature it follows that it cannot provide the necessary technical relationship between the identified inventions. Therefore the claims do not satisfy the requirement of unity of invention *a posteriori*.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

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This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report			Patent Family Member			
WO 03018062	CA	2458856	CN	1578677	EP	1427447
	MX	PA04001828	US	2005042303		
WO 0205852	AU	72202/01	CA	2382560	CN	1388760
	EP	1301209	GB	2368525	NZ	517359
	US	2003180382	US	2005267069	US	2006178342
	ZA	200201561				
WO 0041730	AU	24231/00	CA	2370003	CN	1336828
	EP	1140198	NZ	512676	ZA	200105492
WO 9720564	AU	76878/96	BR	9611671	CA	2164260
	CA	2173037	EP	0869798	HU	9901935
	NO	982441	PL	326970	ZA	9610039
WO 9530423	AP	175	AP	448	AP	475
	AP	476	AP	618	AU	14850/97
	AU	23008/95	AU	24023/95	AU	31595/95
	AU	34888/93	AU	34889/93	AU	42732/97
	AU	48126/93	AU	52274/93	AU	64222/94
	AU	64330/90	AU	70224/96	AU	72721/96
	BR	9006924	BR	9307221	CA	2042034
	CA	2061566	CA	2061703	CA	2079205
	CA	2122519	CA	2122551	CA	2131130
	CA	2145605	CA	2268476	CN	1051503
	CN	1078388	CN	1084064	CN	1092654
	CN	1130532	CN	1151118	CZ	9300229
	CZ	9300230	CZ	9500662	CZ	9603089
	EP	0445255	EP	0626863	EP	0626864
	EP	0656213	EP	0661981	EP	0758246
	EP	0760667	EP	0778776	EP	0952855
	FI	943789	HK	35397	HK	44797
	HK	1005982	HK	1005983	HK	1005985
	HU	64699	HU	70440	HU	73637
	HU	75089	HU	75868	HU	76846
	HU	9500650	HU	9500651	HU	9500652

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HU 9500656	IL 95745	IN 171745
IN 175918	IN 178280	IN 179130
IN 181288	IN 181289	IN 182267
IN 182348	IN 182376	LT 1582
MD 960294	MD 960307	MX 9300904
MX 9300905	MX 9305887	NO 911952
NO 943044	NO 951122	NZ 249071
NZ 249072	NZ 255978	NZ 299280
NZ 299281	NZ 299942	NZ 335259
PL 308201	SG 48845	SG 49658
SG 49874	SG 52416	SK 11093
SK 11193	SK 36895	SK 137996
SK 459890	US 5614506	US 5639738
US 5792753	US 5811410	US 5817642
US 5817644	US 5824658	US 5827834
US 5830882	US 5834444	US 5852002
US 5910489	US 5914314	US 5914322
US 5929048	US 5932560	US 5942498
US 5962433	US 5972906	US 5977088
US 5985850	US 5985851	US 5990095
US 5990096	US 6017900	US 6022866
US 6048844	US 6069135	US 6087344
US 6103704	US 6114314	US 6136793
US 6140312	US 6147059	US 6194392
US 6218373	US 6475795	US 6852708
US 2002077314	US 2003036525	US 2004019011
US 2006128655	WO 9104058	WO 9316732
WO 9316733	WO 9407505	WO 9526193
WO 9529683	WO 9606622	WO 9817320
ZA 9007564	ZA 9301174	ZA 9307068
ZA 9507223		

WO 9104058

AP 175	AP 448	AP 475
AP 476	AP 618	AP 9000206
AP 9300491	AP 9300492	AP 9300568
AP 9500756	AT 131068	AT 141054
AT 200736	AT 227587	AT 244020
AU 670117	AU 674894	AU 674894

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Information on patent family members

International application No.

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AU	696373	AU	702929	AU	739601
AU	768058	AU	14850/97	AU	23008/95
AU	24023/95	AU	31595/95	AU	34888/93
AU	34889/93	AU	42732/97	AU	48126/93
AU	52274/93	AU	64222/94	AU	64330/90
AU	70224/96	AU	72721/96	BR	9006924
BR	9307221	CA	1340994	CA	2042034
CA	2061566	CA	2061566	CA	2061703
CA	2061703	CA	2079205	CA	2079205
CA	2122519	CA	2122519	CA	2122551
CA	2131130	CA	2145605	CA	2268476
CN	1051503	CN	1057908	CN	1078388
CN	1084064	CN	1092654	CN	1101228
CN	1103219	CN	1130532	CN	1151118
CZ	288986	CZ	290534	CZ	290637
CZ	9300229	CZ	9300230	CZ	9500662
CZ	9603089	DE	69024039	DE	69034018
DE	69303931	DE	69330180	DE	69333072
DE	69634993	DK	445255	DK	626863
DK	626864	DK	661981	DK	656213
EP	445255	EP	626863	EP	626864
EP	656213	EP	661981	EP	758246
EP	760667	EP	778776	EP	952855
ES	2080837	ES	2091031	ES	2156124
ES	2186693	ES	2202311	FI	113522
FI	912470	FI	943789	GR	3021171
GR	3036164	HK	35397	HK	44797
HK	1005982	HK	1005983	HK	1005985
HU	64699	HU	70440	HU	73637
HU	75089	HU	75868	HU	76846
HU	211689	HU	211698	HU	211823
HU	211953	HU	220758	HU	907339
HU	9303282	HU	9303283	HU	9500650
HU	9500651	HU	9500652	HU	9500656
HU	9500857	HU	9602965	IL	95745
IL	104796	IL	104797	IL	107087
IL	114914	IN	171745	IN	175918

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International application No.

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IN	178280	IN	179130	IN	181288
IN	181289	IN	182267	IN	182348
IN	182376	JP	3256761	JP	3742955
JP	4504579	JP	7506812	JP	7507054
JP	8506797	JP	9512537	JP	9512797
JP	10504828	LT	1582	LT	3545
MD	960294	MD	960307	MX	9300904
MX	9300905	MX	9305887	NO	309457
NO	312939	NO	911952	NO	943044
NO	951122	NZ	249071	NZ	249072
NZ	299942	NZ	335259	PL	173211
PL	308201	PT	626863	PT	626864
RO	112812	RO	117499	RU	2146139
RU	2162327	SG	48845	SG	49658
SG	49874	SG	52416	SK	11093
SK	11193	SK	36895	SK	137996
SK	459890	US	5614506	US	5639738
US	5792753	US	5811410	US	5817642
US	5817644	US	5824658	US	5827834
US	5830882	US	5834444	US	5852002
US	5910489	US	5914314	US	5914322
US	5929048	US	5932560	US	5942498
US	5962433	US	5972906	US	5977088
US	5985850	US	5985851	US	5990095
US	5990096	US	6017900	US	6022866
US	6048844	US	6069135	US	6087344
US	6103704	US	6114314	US	6136793
US	6140312	US	6147059	US	6194392
US	6218373	US	6475795	US	6852708
US	2002077314	US	2003036525	US	2004019011
US	2006128655	WO	9104058	WO	9104058
WO	9316732	WO	9316733	WO	9407505
WO	9526193	WO	9529683	WO	9530423
WO	9606622	WO	9817320	ZA	9007564
ZA	9301174	ZA	9307068	ZA	9507223

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX